K113712

MAR 15 2012

5. 510(k) SUMMARY AS REQUIRED BY SECTION 807.92(C)

Submitted by: Mrs. Mitsuko Yoneyama
President

Narishige Co., Ltd.
27-9, Minamikarasuyama 4-chome
Setagaya-ku
Tokyo 157-0062
Japan

Phone: 81-3-3308-8383
Fax: 81-3-3308-8700
E-mail: sales@narishige.co.jp

Date Submitted: November 30, 2011

Device Identification:

Trade Name:	IM-11 Pneumatic Microinjector
Common Name:	Injector
Classification Name:	Assisted Reproduction Micromanipulators and Microinjectors (21 CFR, 884.6150)

Predicate Device:

Narishige Co., Ltd. claims the IM-11 Pneumatic Microinjector as substantially equivalent to predicate the IM-9C Pneumatic Injector, Premarket Notification 510(k) Number: K001910.

Device Description:

The IM-11 Pneumatic Microinjector is used for Intracytoplasmic Sperm Injection (ICSI) procedures to aspirate and inject sperm into oocytes, and to hold oocytes during the ICSI procedure.

The IM-11 Pneumatic Microinjector is a manually-operated pneumatically-actuated screw-driven microinjector incorporating coarse and fine control knobs. The coarse control knob is used to perform coarse movement operation while the fine control knob is used to perform fine movement operation. It is easy to use simply by turning the control knob clockwise for injection and counterclockwise for aspiration.

The IM-11 Pneumatic Microinjector is a component part of a micromanipulator system.

Examples of roles the IM-11 plays in the ICSI would be:
- holding an oocyte
- aspirating a sperm into the injection pipette
- injecting a sperm into an oocyte

Intended Use:

The IM-11 Pneumatic Microinjector is used for Intracytoplasmic Sperm Injection (ICSI) procedures to aspirate and inject sperm into oocytes, and to hold oocytes during the ICSI procedure.

Substantial Equivalence:

Narishige Co., Ltd. claims the IM-11 Pneumatic Microinjector as substantially equivalent to predicate the IM-9C Pneumatic Injector, Premarket Notification 510(k) Number: K001910.

Technological Characteristics:

The IM-11 and the predicate device IM-9C (K001910) are both manually-operated pneumatically-actuated screw-driven injectors. They are both a part of the micromanipulator system and can be used interchangeably.

Comparisons of the technological characteristics between the IM-11 and the predicate device IM-9C are summarized in the table on the next page.

Comparison Table

	IM-11 Pneumatic Microinjector (Subject Device)	IM-9C Pneumatic Injector (Predicate Device)
Maximum Operating Range	40mm (coarse and fine combined) 30mm by Coarse Control Knob 17mm by Fine Control Knob	53mm
Distance the Plunger travels and Volume controlled by One Rotation of Control Knob	Approximately 6.0mm and 1ml (theoretical value) for Coarse Control Knob. Approximately 1.4mm and 250ul (theoretical value) for Fine Control Knob.	Approximately 6.0mm and 480ul
Pressure Relief Valve	Pressure Relief Valve: Function: Allows pressure to escape and neutralizes the pressure inside the Microinjector. How to Use: Simply press the lever on the Pressure Relief Valve.	Tube Connector (with Multipurpose Valve): Function: Allows pressure to escape and neutralizes the pressure inside the Injector. How to Use: Loosen the Valve Plug on the Tube Connector.
Syringe	Metal Syringe: 7,900ul	Metal Syringe: 4,240ul
Dimensions	167-214(W)x55(D)x78(H)mm	136-189(W)x55(D)x74(H)mm
Weight	680g	640g
Intended Use	The IM-11 Pneumatic Microinjector is used for Intracytoplasmic Sperm Injection (ICSI) procedures to aspirate and inject sperm into oocytes, and to hold oocytes during the ICSI procedure.	The IM-9C Pneumatic Injector is used to inject solutions into organisms, aspirate fluid samples from tissues or hold cells and eggs by aspiration onto the end of a holding pipette.

Conclusions:
Both the IM-11 and the IM-9C are manually-operated pneumatically-actuated screw-driven injectors. They are made for the same purposes and share almost the same intended use. Narishige Co., Ltd. claims the IM-11 Pneumatic Microinjector is as safe, as effective, and performs as well as the legally marketed device: IM-9C Pneumatic Injector; Premarket Notification 510(k) Number: K001910.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mrs. Mitsuko Yoneyama
President
Narishige Co., Ltd.
27-9, Minamikarasuyama 4-chome, Setagaya-ku
TOKYO 157-0062
JAPAN

MAR 15 2012

Re: K113712
Trade/Device Name: IM-11 Pneumatic Microinjector
Regulation Number: 21 CFR§ 884.6150
Regulation Name: Assisted reproduction micromanipulators and microinjectors
Regulatory Class: II
Product Code: MQJ
Dated: November 30, 2011
Received: December 19, 2011

Dear Mrs. Yoneyama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use:

510(k) Number (if known): K113712

Device Name: IM-11 Pneumatic Microinjector

Indications for Use: The IM-11 Pneumatic Microinjector is used for Intracytoplasmic Sperm Injection (ICSI) procedures to aspirate and inject sperm into oocytes, and to hold oocytes during the ICSI procedure.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113712